

Exhibit 12

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEMS MDL No. 2327
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO: ALL CASES

CONFIDENTIAL - SUBJECTIVE TO PROTECTIVE ORDER

VIDEOTAPED DEPOSITION OF

PIET HINOUL, MD

VOLUME 3

January 13, 2014

REPORTED BY: LANCE A. BOARDMAN

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1 A. Correct.

2 Q. Okay. Do you know when that
3 was?

4 A. I don't. It must have been --
5 no, I don't know.

6 Q. Can you give me a range?

7 A. I would estimate it must have
8 been around 2003, '4.

9 Q. From a design standpoint, do
10 you know the reason why the TVT classic, the
11 retropubic TVT, began to be offered in a
12 laser-cut mesh?

13 A. Well, there was voice of
14 customer that when you have the tape
15 mechanically cut, because the way it is
16 knitted, little particles would fray at the
17 edges. And surgeons didn't like that from a
18 visual perspective, and so they asked for it
19 to not to have that.

20 And when you cut it by laser,
21 you don't have -- you don't have that because
22 there's a heat component to it.

23 Q. Do I understand correctly that
24 one of the things your company was hearing
25 from surgeons was that when they would cut

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1 the TVT mesh, there would be particle loss?
2 They would actually see particles come off
3 the mesh?

4 A. When would they cut the TVT?

5 Q. I was just asking: Was
6 there -- was there some particle loss that
7 was being reported with TVT mesh?

8 A. So that is the fraying I'm
9 referring to, is the little particles on the
10 edges that would come loose.

11 Q. Okay. And doctors did not want
12 particles of polypropylene coming loose
13 inside their patients' bodies, correct?

14 A. I think, you know, surgeons,
15 not all surgeons, necessarily understand what
16 the textile involved or the science behind
17 the textile. Maybe they were worried that it
18 would disintegrate and become loose.

19 You know, if you have a sweater
20 and you pull on it at the end, you can get
21 the whole sweater. And I think that was
22 their worry, which was not the case because
23 it was only just the end points of the mesh
24 on the sides that were coming loose. It
25 wouldn't impact the other rows.

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1 Q. Did your company study the
2 clinical impact of particles of the
3 machine-cut TVT retropubic mesh coming loose
4 in a patient? Did your company ever study
5 whether that could have a clinical impact?

6 A. Well, we didn't have to study
7 that because we studied the implantation of
8 full meshes, right? It's the same -- it's
9 the same material.

10 Q. Here's my question.

11 Move to strike.

12 Did your company ever study the
13 specific issue I just raised in my question?

14 A. Yes.

15 Q. The clinical impact of
16 particles of the TVT machine-cut mesh --

17 A. Yes.

18 Q. -- coming loose in the body?

19 A. Yes, because we could refer to
20 polypropylene implantation studies. It's the
21 same material.

22 Q. What study would tell you about
23 the clinical impact of having particles of
24 the TVT machine-cut mesh in a person's body?

25 A. Any study on which we study

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1 polypropylene suture or anything of that
2 sort, we would be able to -- we would be able
3 to refer to.

4 Q. So to the extent that you have
5 studies that show what the foreign body
6 reaction is to polypropylene in the body in
7 general, that would apply to the particles,
8 correct?

9 A. I would agree.

10 Q. Okay. Looking at this
11 paragraph here on page 42, the very bottom of
12 it, at the bottom right corner it says:
13 Quality of life was poorly reported using a
14 variety of instruments, thus precluding
15 metaanalysis.

16 A. Mm-hmm.

17 Q. That's basically saying that
18 quality of life was measured in so many
19 different ways that you couldn't generalize
20 the findings to form any conclusion?

21 A. Yes. In 2009, that certainly
22 was the case. You know, urogynecology is a
23 pretty new field in gynecology, and so
24 there's still lots of new signs emerging.
25 One of them is what is the best way to